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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,843	06/15/2001	Xue-Feng Pei	SYM 114	8772
7590 04/21/2004 KEITH A. JOHNSON TRANSGENOMIC, INC 12325 EMMET STREET OMAHA, NE 68164			EXAMINER COLEMAN, BRENDA LIBBY	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,843	PEI ET AL.	
	Examiner	Art Unit	
	Brenda Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,6,8,10,11,13,16-18,20,21,23,25,26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,8,10,11,13,16-18,20,21,23,25,26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3, 5, 6, 8, 10, 11, 13, 16-18, 20, 21, 23, 25, 26 and 28 are pending in the application.

This action is in response to applicants' amendment dated November 28, 2003. Claims 1, 2, 5, 10, 11, 13, 16, 17, 20, 25, 26 and 28 have been amended and claims 4, 7, 9, 12, 14, 15, 19, 22, 24, 27, 29 and 30 have been canceled.

Response to Arguments

Applicants' arguments filed November 28, 2003 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 1 of claims 3, 4, 6-15, 18, 19 and 21-30 of the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled h), j), k), t), u), y), ab), ac), ak), al) and am) of the last office action, which are hereby **withdrawn**.
3. With regards to the 35 U.S.C. § 102, anticipation rejection of claims 1-19, 23-27 and 30 labeled paragraph 5 in the last office action, the applicants' arguments have been fully considered but are not found persuasive. The applicants' stated that they have amended the claims to state that one of the substituents of R¹, R³ and R⁴ must be C1-C3-alkoxy or C1-C3-alkylthio group" and that "Ling et al. does not teach or suggest compounds wherein one of the substituents of R¹, R³ and R⁴ must be C1-C3-alkoxy or

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C1-C3-alkylthio group" and thus this reference can neither anticipate nor render obvious the claims as amended. It is noted that claims 1, 2, 10, 11, 16, 17, 25 and 26 have been amended to recite that one of the substituents of R^1 , R^3 and R^4 must be C1-C3-alkoxy or C1-C3-alkylthio group, however, several of the species of claims 5 and 13 are not such that one of the substituents of R^1 , R^3 and R^4 is C1-C3-alkoxy or C1-C3-alkylthio group, but rather instant R^2 is methoxy or methylthio.

Claims 5, 6 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Ling et al., WO 97/28135 (U.S. equivalent 6,200,970), for reasons of record and stated above.

4. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-30 labeled paragraph 7 of the last office action, the applicant's remarks have been fully considered but they are not persuasive. The applicants' stated that they have amended the claims to state that one of the substituents of R^1 , R^3 and R^4 must be C1-C3-alkoxy or C1-C3-alkylthio group" and that "Ling et al. does not teach or suggest compounds wherein one of the substituents of R^1 , R^3 and R^4 must be C1-C3-alkoxy or C1-C3-alkylthio group" and thus this reference can neither anticipate nor render obvious the claims as amended. It is noted that claims 1, 2, 10, 11, 16, 17, 25 and 26 have been amended to recite that one of the substituents of R^1 , R^3 and R^4 must be C1-C3-alkoxy or C1-C3-alkylthio group, however, several of the species of claims 5 and 13 are not such that one of the substituents of R^1 , R^3 and R^4 is C1-C3-alkoxy or C1-C3-alkylthio group, but rather instant R^2 is methoxy or methylthio.

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Claims 5, 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al., WO 97/28135 (U.S. equivalent 6,200,970), for reasons of record and stated above.

5. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 8 of claims 1-4, 8-12, 16, 23-25 and 30 of the last office action, which is hereby **withdrawn**.

6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claims 1, 8-10 and 15 of the last office action, which are hereby **withdrawn**.

7. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection labeled paragraph 9 of claims 1, 8-10 and 15 of the last office action, which is hereby **withdrawn**.

In view of the amendment dated March 20, 2003, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 1-3, 5, 6, 8, 10, 11, 13, 16-18, 20, 21, 23, 25, 26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

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point out and distinctly claim the subject matter which applicant regards as the

invention. The following reasons apply:

- a) Claims 1 and 8 are vague and indefinite in that it is not known what is meant by the definition of R^1 , R^2 , R^3 and R^4 where R^1 , R^2 , R^3 and R^4 are $R^{13}S$, which does not indicate the point of attachment. (See claim 1)
- b) Claims 1-3, 8, 10 and 11 are vague and indefinite in that it is not known what is meant by the definition of the substituents on the phenyl ring of R^5 , R^6 , R^7 and R^8 where the phenyl ring is substituted by $R^{14}CO$ or $R^{14}NHCO$, which does not indicate the point of attachment. (See claims 1 and 10)
- c) Claims 1-3, 8, 10 and 11 are vague and indefinite in that it is not known what is meant by the definition of R^9 where R^9 is $R^{15}R^{16}N(CR^{17})-$. The nitrogen atom contains four bonds. (See claims 1, 2, 10 and 11)
- d) Claims 1, 8 and 10 are vague and indefinite in that it is not known what is meant by the definition of R^9 where R^9 is $NC-(CH_2)_n-$. The variable n should be a subscript. (See claims 1 and 10)
- e) Claims 1, 8 and 10 are vague and indefinite in that it is not known what is meant by the definition of R^8 and R^9 where R^8 and R^9 taken together can be $-(CH_2)_mCH_2(R^{15})NCO-$, $-(CH_2)_m-CH_2-OCO-$, or $-(CH_2)_mCH_2CH_2CO-$. The variable m should be a subscript. (See claims 1 and 10)
- f) Claims 1, 8 and 10 are vague and indefinite in that it is not known what is meant by the definition of R^{10} and R^{11} where R^{10} and R^{11} are $R^{15}R^{16}N(CR^{17})-$. The nitrogen atom contains four bonds. (See claims 1 and 10)

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- g) Claims 1-3, 8, 10 and 11 are vague and indefinite in that it is not known what is meant by the definition of R^{15} and R^{16} where R^{15} and R^{16} are C3-C10, alkenyl. It is believed that the applicants intended C3-C10-alkenyl. (See claims 1 and 10)
- h) Claims 5, 6 and 13 are vague and indefinite in that it is not known what is meant by the second occurrence of the eleventh species, i.e. lines 13-14 of page 8 in the amendment filed November 28, 2003. (See claims 5 and 13)
- i) Claims 5, 6 and 13 recite the limitation "8-methoxy" in the nomenclature of the eleventh **through** the twentieth species. There is insufficient antecedent basis for this limitation in the claim. (See claims 5 and 13)
- j) Claims 5, 6 and 13 are vague and indefinite in that it is not known what is meant by the nomenclature of the twenty third species, i.e. 1-(4-Aminophenyl)-3,5-dihydro-4-methyl-3-ethylcarbamoyl-7-methylthio-5H-2,3-benzodiazepine. (See claims 5 and 13)
- k) Claims 5, 6 and 13 are vague and indefinite in that it is not known what is meant by the nomenclature of the twenty ninth species, i.e. 1-(4-Aminophenyl)-8-amino-3,5-dihydro-4-methyl-3-propylcarbamoyl-7-methylthio-5H-2,3-benzodiazepine. (See claims 5 and 13)
- l) Claims 5, 6 and 13 recite the limitation "8-methylthio" in the nomenclature of the thirty first **through** the fortieth species. There is insufficient antecedent basis for this limitation in the claim. (See claims 5 and 13)

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- m) Claim 10 is vague and indefinite in that it is not known what is meant by the definition of R^{12} where R^{12} is $R^{14}CONH0$. It is believed that the applicants intended $R^{14}CONH-$. (See claim 10)
- n) Claim 11 is vague and indefinite in that it is not known what is meant by the "or" in the definition of R^9 of the Markush group. (See claim 11)
- o) Claim 13 is vague and indefinite in that it is not known what is meant by the nomenclature of the thirty second species, i.e. 1-(4-Aminophenyl)-3,5-dihydro-4-methyl-3-methylcarbamoyl-**S**-methylthio-5H-2,3-benzodiazepine. (See claim 13)
- p) Claim 13 is vague and indefinite in that it is not known what is meant by the nomenclature of the thirty third species, i.e. 1-(4-Aminophenyl)-3,5-dihydro-4-methyl-3-ethylcarbamoyl-8-methylthio-5H-2,2-benzodiazepine. (See claim 13)
- q) Claims 16, 23 and 25 are vague and indefinite in that it is not known what is meant by the definition of R^2 where R^2 is $R^{13}O$ or $R^{14}NHCO_2$, which does not indicate the point of attachment. (See claims 16 and 25)
- r) Claims 16, 23 and 25 are vague and indefinite in that it is not known what is meant by the definition of R^3 where R^3 is $R^{13}O$ or $R^{14}NHCO_2$, which does not indicate the point of attachment. (See claims 16 and 25)
- s) Claim 16-18 and 23 are vague and indefinite in that it is not known what is meant by the definition of R^8 . There is no variable R^8 in formula II. (See claim 16)

- t) Claims 16-18, 23, 25 and 26 are vague and indefinite in that it is not known what is meant by the definition of the substituents on the phenyl ring of R^5 , R^6 , R^7 and R^8 where the phenyl ring is substituted by $R^{14}CO$ or $R^{14}NHCO$, which does not indicate the point of attachment. (See claims 16 and 25)
- u) Claims 20 and 21 are vague and indefinite in that it is not known what is meant by the nomenclature of the second species, i.e. 1-(4-Aminophenyl)-8-amino-4-methyl-7-methoxy-5H-2,2-benzodiazepine. (See claim 20)
- v) Claims 20 and 21 recite the limitation "8-methoxy" in the nomenclature of the fourth species. There is insufficient antecedent basis for this limitation in the claim. (See claim 20)
- w) Claims 20 and 21 recite the limitation "8-methylthio" in the nomenclature of the seventh and eighth species. There is insufficient antecedent basis for this limitation in the claim. (See claim 20)
- x) Claim 25 is vague and indefinite in that it is not known what is meant by the definition of R^{18} and R^{19} where R^{18} and R^{19} are CF_3 . It is believed that the point of attachment should not be subscripted.
- y) Claim 28 recites the limitation "8-methoxy" in the nomenclature of the fourth species. There is insufficient antecedent basis for this limitation in the claim. (See claim 28)
- z) Claim 28 recites the limitation "8-methylthio" in the nomenclature of the seventh and eighth species. There is insufficient antecedent basis for this limitation in the claim. (See claim 28)

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman
Primary Examiner Art Unit 1624
April 16, 2004